

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SEBELA PHARMACEUTICALS INC.,

Plaintiff,

v.

**MESORA PHARMA, LLC,
PYRAMID MANAGEMENT, LLC, and
JOHN DOES 1-10.**

Defendant.

CIVIL ACTION NO.

Demand For Jury Trial

COMPLAINT

Plaintiff Sebela Pharmaceuticals Inc. (“Sebela” or “Plaintiff”) for its Complaint against Defendant Mesora Pharma, LLC (“Mesora”), Defendant Pyramid Management, LLC (“Pyramid”) and Defendants John Does 1-10 (collectively, “Doe Defendants” and, together with Mesora and Pyramid, the “Defendants”) hereby states and alleges as follows:

THE PARTIES

1. Sebela is a corporation organized under the laws of the State of Delaware with a principal place of business in Roswell, Georgia.
2. Upon information and belief, Defendant Mesora is a Nevada limited liability company.
3. Upon information and belief, Mesora is a privately owned pharmaceutical marketing company, whose products are advertised and marketed through all major distribution channels in the United States.
4. Upon information and belief, Defendant Pyramid is a Wyoming corporation with an address of 318 McMicken St., Rawlins, WY, 82301-2887.

5. Upon information and belief, Defendant Pyramid is a manager and officer of Defendant Mesora and, as its manager, is a moving, acting, and conscious force behind the false and misleading activities of Defendants alleged herein.

6. Defendants John Does 1-10 are other persons or entities involved in the false and misleading activities alleged herein.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1332, and 1338, and 15 U.S.C. §§ 1116 and 1121, as this case arises under the Lanham Act. This Court also has supplemental jurisdiction over Sebela's state and common law claims pursuant to 28 U.S.C. § 1367.

8. At all times relevant to this lawsuit, Defendants, and one or more of their agents, have been engaged in the business of advertising, promoting, marketing, distributing, and/or selling, within the State of Delaware and in interstate commerce throughout the United States, the products which are the subject of this Complaint, namely, a hydrocortisone acetate and pramoxine hydrochloride cream called Mezparox-HC that is marketed under National Drug Code ("NDC") number 71850-1812-01 (hereinafter, "Mezparox").

9. The Defendants are subject to personal jurisdiction in Delaware because, upon information and belief, the Defendants transact business and/or advertise or contract to supply services or things in this State; have caused tortious injury in Delaware by an act or omission committed in Delaware; and/or have caused tortious injury in Delaware or outside Delaware by an act or omission outside Delaware, and regularly do or solicit business, engage in a persistent course of conduct in Delaware, and/or derive substantial revenue from things used, sold, and/or consumed in Delaware.

10. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) in that a substantial part of the events giving rise to the claim occurred in this District and, separately, because Defendants are subject to personal jurisdiction in this District.

STATEMENT OF FACTS

A. Sebela's Products

11. Sebela is in the business of developing, marketing, distributing, and selling FDA registered prescription pharmaceutical products in the gastroenterology and dermatology fields.

12. Sebela's predecessor in interest, Ferndale Laboratories, Inc. (later reorganized as Ferndale Pharma Group, Inc.) ("Ferndale"), developed, manufactured, and marketed a line of prescription products containing varying dosages of hydrocortisone acetate and pramoxine hydrochloride in cream, lotion, or ointment form (collectively, the "HCA/Pram Products"), which are currently marketed under the trademarks and trade names "PRAMOSONE" ("PRAMOSONE") and "ANALPRAM" ("ANALPRAM")

13. The PRAMOSONE and ANALPRAM prescription products have been continuously on the market for over 30 years and are topical corticosteroids with anti-inflammatory, antipruritic, and vasoconstrictive qualities and are available only by prescription.

14. In the 1970s, Ferndale submitted and received Food and Drug Administration ("FDA") approval of several ANDAs for a number of hydrocortisone acetate and pramoxine hydrochloride products, including the HCA/Pram Products.

15. On July 1st, 1988, the FDA published in the Federal Register a Notice of Opportunity for a Hearing ("NOOH") regarding the regulatory status of fixed combination drug products that contain hydrocortisone acetate and pramoxine hydrochloride, which included Ferndale's HCA/Pram Products. (53 Fed. Reg. 25013 (July 1, 1988)).

16. Under the NOOH, the FDA required the ANDA holders to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

17. In response to the 1988 FDA notice, Ferndale submitted a timely hearing request for the HCA/Pram Products. This request for hearing was affirmed by Ferndale Laboratories, Inc., on January 3rd, 2011. (77 Fed. Reg. 43337 (July 24, 2012)).

18. FDA has confirmed that the HCA/Pram Products are subject to the NOOH proceedings.

19. Only the parties who had hydrocortisone acetate and pramoxine hydrochloride products on the market at the time of the NOOH in 1988 and who have continued to affirm their right for hearing through the proper legal channels have the legal authority to market the HCA/Pram Products.

20. In 2013, Sebela purchased the right, title, and interest in the HCA/Pram Products from Ferndale. Ferndale continues to act as the manufacturer of these products.

21. In addition to product rights, Sebela acquired from Ferndale all of the regulatory rights and history concerning the HCA/Pram Products, including historical correspondence between Ferndale and the FDA.

22. Having acquired these products from Ferndale in 2013, Sebela received and asserts the same exclusive legal rights to a hearing and other regulatory procedures under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and which assertion has been affirmed by the FDA.

23. One of the HCA/Pram Products marketed by Sebela is hydrocortisone acetate 2.5% pramoxine hydrochloride 1% cream, which is marketed under the PRAMOSONE and

ANALPRAM trademarks and trade names (hereinafter, “PRAMOSONE Cream”).

24. PRAMOSONE Cream is a topical preparation containing hydrocortisone acetate 2.5% w/w and pramoxine hydrochloride 1% w/w in a hydrophilic cream base containing stearic acid, cetyl alcohol, Aquaphor®, isopropyl palmitate, polyoxyl 40 stearate, propylene glycol, potassium sorbate, sorbic acid, triethanolamine lauryl sulfate, and purified water.

25. Sebela has expended significant resources in developing, manufacturing, and marketing its prescription products in compliance with existing laws and regulations and derives substantial profits through sales of PRAMOSONE Cream.

26. Sebela enjoys a strong reputation and has developed substantial goodwill among suppliers, medical professionals, pharmacists, regulators, consumers and others in connection with PRAMOSONE Cream, which is manufactured in accordance with current good manufacturing practices (“cGMP”).

27. Sebela maintains contractual relationships with pharmaceutical manufacturers, distributors, and/or suppliers in order to make and sell PRAMOSONE Cream. These contractual relationships result in economic benefits to Sebela, and will continue to do so in the future. These contractual relationships are standard for the industry.

B. Defendants’ Unauthorized “Generic” Product

28. Upon information and belief, Mesora is a drug distributor that markets and advertises unauthorized “knock-off” versions of successful brand-name drugs.

29. Upon information and belief, as manager of Mesora, Defendant Pyramid is a moving, acting, and conscious force behind the false and misleading activities of Defendants alleged herein.

30. Upon information and belief, Defendants Mesora and Pyramid have taken

conscious and willful steps to hide the identities of the owners of Mesora and its other members and managers.

31. Upon information and belief, those anonymous defendants, named herein as Doe Defendants, are moving, acting, and conscious forces behind the false and misleading activities of Defendants alleged herein.

32. Upon information and belief, on or around November, 2017, Defendants saw an opportunity to exploit Sebela's success by marketing Mezparox as a "generic" version of Sebela's PRAMOSONE Cream.

33. Upon information and belief, Defendants do not market their drug products to physicians. Rather, they advertise and market their drug products to drug wholesalers, distributors, pharmacies, insurers, and others in the pharmaceutical industry as generic substitutes for brand-name drugs to disrupt the market for the brand products and generate sales, in this instance, by encouraging improper "generic" substitution of its products for PRAMOSONE Cream, such as improper automatic "generic" substitution of its products at the pharmacy level.

C. Defendants Advertise and Market Mezparox as a Generic Substitute for PRAMOSONE Cream

34. Upon information and belief, Defendants, directly and by implication, have represented and continue to represent to wholesalers, distributors, pharmacies, and other members of the pharmaceutical industry that Mezparox is a "generic equivalent" of Sebela's PRAMOSONE Cream and substitutable therefore.

35. Upon information and belief, Mezparox is currently listed in wholesaler drug catalogs and databases as a generic equivalent of PRAMOSONE Cream, when it is not.

36. Upon information and belief, Defendants also advertise and promote its products as a “generic equivalent” of PRAMOSONE Cream on pharmaceutical drug databases and price lists, including Medi-Span (hereinafter, together with the wholesaler drug catalogs and databases, the “Drug Databases”).

37. The Drug Databases are specialized marketing channels which are used nationwide by manufacturers to advertise and promote their products, and by wholesalers, pharmacies, pharmacists, insurers, health care professionals, and others in the pharmaceutical industry to evaluate medications that are currently on the market and determine whether “generic” versions of brand-name products are available.

38. Upon information and belief, through its marketing of Mezparox, Defendants are also representing, expressly or impliedly, that Mezparox is properly substitutable for Sebela’s PRAMOSONE Cream, and/or properly automatically substitutable for Sebela’s PRAMOSONE Cream at the pharmacy level.

39. Upon information and belief, based upon Defendants’ false and misleading representations, wholesalers, distributors, pharmacies, pharmacists, insurers and others in the industry, are being deceived into believing that Mezparox has been reviewed or approved by the FDA as a generic equivalent that is substitutable for PRAMOSONE Cream.

D. Mezparox is not a Generic Equivalent of or Substitutable for PRAMOSONE Cream

40. Notwithstanding Defendants’ advertising and promotional efforts, Mezparox is a new product that has not been reviewed or approved by the FDA and is not a “generic equivalent” of Sebela’s PRAMOSONE Cream, nor is it substitutable therefor.

41. True generic drugs are “therapeutically equivalent” to their branded rivals. “Therapeutically equivalent” drugs must be both “pharmaceutically equivalent” (that is, they

have identical active ingredients, strength, and dosage form) and “bioequivalent” (that is, the bioavailability--the rate and extent to which the active ingredients are absorbed by the body--is the same).

42. To market a drug as a “generic,” the drug manufacturer or distributor must submit an application to the FDA summarizing the testing it has performed to establish therapeutic equivalence between the referenced drug and the generic version of the drug.

43. The majority of states, including Delaware, prohibit substitution of a drug for a prescribed brand-name drug unless the substitute is therapeutically equivalent to the prescribed drug.

44. In many of these states, including Delaware, substitution is guided by the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the “Orange Book”). In these states, products which are not listed in the Orange Book may not be lawfully substituted. Products which are listed in the Orange Book as therapeutic equivalents can be automatically substituted at the pharmacy level without the input of the prescribing physician.

45. Notwithstanding Defendants’ marketing, Mezparox is not a generic equivalent to or substitutable for PRAMOSONE Cream.

46. Mezparox has not been reviewed or approved by the FDA as a “generic” of PRAMOSONE Cream or any other product.

47. Mezparox is not listed as therapeutically equivalent to PRAMOSONE Cream in the Orange Book.

48. Indeed, upon information and belief, Mezparox is not listed on any FDA website, nor have Defendants registered with the FDA.

49. Upon information and belief, Mezparox is not therapeutically equivalent to the PRAMOSONE Cream product.

50. Upon information and belief, Defendants have not tested Mezparox for therapeutic equivalence to PRAMOSONE Cream.

51. Additionally, upon information and belief, Mezparox is an unapproved product which Defendants did not market prior to 2017.

52. Unlike Sebela, Defendants are not a party to the NOOH administrative process for HCA/Pram Products, which has been in place since 1988.

53. In its 2011 Compliance Policy Guide, the FDA confirmed that any unapproved drug product coming to market for the first time after September 19, 2011 was illegal and subject to immediate legal action by the FDA.

54. Defendants' marketing efforts have misled consumers into believing that Mezparox is generic to and substitutable for PRAMOSONE Cream, when in fact it is not.

55. As a result of Defendants' false and misleading representations about the product, Sebela's goodwill is being harmed and will continue to be harmed, Sebela will suffer eroding sales of its products, and, upon information and belief, Mezparox will be improperly substituted by pharmacists who receive prescriptions written for PRAMOSONE Cream.

56. Additionally, Sebela does not and cannot control the safety, effectiveness, or quality of Mezparox. Doctors and patients who suffer bad or disappointing experiences such as denial of coverage for PRAMOSONE Cream, or suffer adverse reactions with Mezparox, are likely to attribute such negative experiences to Sebela and PRAMOSONE Cream, thereby further harming PRAMOSONE Cream sales and Sebela's goodwill.

57. Upon information and belief, this risk is even greater in light of the conscious and

knowing efforts of Defendants to hide the true ownership of Defendant Mesora.

E. The Resulting Harm to Sebela

58. Upon information and belief, Defendants false representations about Mezparox, directly or indirectly, deceive members of the pharmaceutical industry into believing that it is generically equivalent to and substitutable for PRAMOSONE Cream, when in fact it is not.

59. Upon information and belief, wholesalers, pharmacies, pharmacists, insurers, health care professionals, and others in the pharmaceutical industry are likely to be deceived and are actually being deceived by Defendants' false and misleading representations about Mezparox.

60. Upon information and belief, Defendants know that their marketing of Mezparox is likely to deceive and is actually deceiving drug wholesalers, distributors, pharmacies, pharmacists, and others in the industry about the nature, characteristics, and qualities of Mezparox and will cause improper refusal of insurance coverage for PRAMOSONE Cream, loss of formulary listing or reduced formulary coverage for PRAMOSONE Cream, and improper substitution of Mezparox for PRAMOSONE Cream.

61. Upon information and belief, Defendants have not only engaged in the false advertising and marketing of Mezparox, but have also done so willfully. This is evidenced by their conscious and willful attempts to hide the true ownership of Defendant Mesora.

62. Through these and other false and misleading representations, Defendants have and will continue to cause harm to the reputation and goodwill that Sebela and Ferndale have developed over thirty (30) years in the industry and, upon information and belief, have caused and will continue to cause Sebela to lose both revenue and market share.

COUNT I

False Advertising Under the Lanham Act – 15 U.S.C. § 1125(a)

63. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs of this Complaint as though set forth fully herein.

64. As noted above, Defendants, in the course of advertising and marketing the Mezparox product, have used, in interstate commerce and in commercial advertising, false and misleading representations of fact that misrepresent the true nature, characteristics, and health risks of its product.

65. Defendants have made numerous false or misleading representations of fact, including that Mezparox is a generic equivalent to and substitutable for PRAMOSONE Cream.

66. Defendants' actions and representations with respect to Mezparox, including listing the product with the Drug Databases, constitute commercial advertising or promotion.

67. Defendants' misrepresentations about Mezparox relate to inherent qualities or characteristics of Mezparox.

68. Defendants' false and misleading representations are material in that they are likely to influence the purchasing decisions of wholesalers, third-party payors, pharmacists, health care professionals, insurers, and others in the pharmaceutical industry, as well as patients who use Sebela's products.

69. Defendants' representations have deceived and/or have the tendency to deceive a substantial segment of its intended audience.

70. But for Defendants' false and/or misleading statements, wholesalers, third-party payors, pharmacists, health care professionals, patients, insurers, and others in the pharmaceutical industry would not list, purchase, distribute, prescribe, cover, or use Mezparox.

71. Upon information and belief, Defendants' actions have been willful and deliberate.

72. As a direct and proximate result of Defendants' actions, Sebela has and will continue to suffer damage to its business, reputation, goodwill, and the loss of sales, profits, and customers.

73. Defendants' actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Sebela's business, reputation, and goodwill, unless enjoined by this Court.

74. Pursuant to 15 U.S.C. § 1116, Sebela is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

75. Pursuant to 15 U.S.C. § 1117, Sebela is entitled to recover treble damages sustained by Defendants' actions, an accounting for profits realized by Mesora, and the costs of this action.

76. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Sebela is entitled to an award of reasonable attorney's fees.

COUNT II

Contributory False Advertising under the Lanham Act - 15 U.S.C. § 1125(a)

77. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs of this Complaint as though set forth fully herein.

78. Upon information and belief, Defendants are knowingly inducing or causing, and/or materially participating in the false and misleading advertising and promotion of Mezparox by Drug Databases, wholesalers, pharmacies, insurers, and/or other members of the pharmaceutical industry as an FDA-approved "generic" product that is therapeutically equivalent

to and/or substitutable for PRAMOSONE Cream.

79. Upon information and belief, Defendants knew and/or intended to participate in the false advertising of Mezparox by Drug Databases, wholesalers, pharmacies, insurers, and/or other members of the pharmaceutical industry.

80. Upon information and belief, Defendants actively and materially furthered such false and misleading advertising and promotion of Mezparox by listing the product with the Drug Databases and by expressly or impliedly representing that Mezparox was equivalent to and/or substitutable for the PRAMOSONE Cream.

81. Such false and misleading representations about Mezparox by Drug Databases, wholesalers, pharmacies, insurers, and/or other members of the pharmaceutical industry have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of Mezparox.

82. Such false and misleading representations about Mezparox by Drug Databases, wholesalers, pharmacies, insurers, and/or other members of the pharmaceutical industry are material and likely to influence the purchasing decisions of wholesalers, third-party payors, pharmacists, health care professionals, insurers, and others in the pharmaceutical industry, as well as patients who use Sebela's products.

83. These false or misleading representations were and are made in interstate commerce.

84. Upon information and belief, Defendants' actions have been willful and deliberate.

85. As a direct and proximate result of Defendants' conduct, Sebela has suffered damages, which includes a loss of reputation, sales, profits and customers.

86. Defendants' actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Sebela's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

87. Pursuant to 15 U.S.C. § 1116, Sebela is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

88. Pursuant to 15 U.S.C. § 1117, Sebela is entitled to recover treble damages sustained by Defendants' actions, an accounting for profits realized by Mesora, and the costs of this action.

89. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Sebela is entitled to an award of reasonable attorney's fees.

COUNT III

Unfair Competition Under the Lanham Act – 15 U.S.C. § 1125(a)

90. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs of this Complaint as though set forth fully herein.

91. By virtue of Defendants' false or misleading representations, as detailed above, Defendants are also liable for unfair competition under the Lanham Act.

92. Defendants' false and/or misleading representations of fact are likely to cause confusion or mistake or to deceive as to Defendants' affiliation, connection or association with Sebela and/or the FDA.

93. Defendants' false and/or misleading representations of fact are also likely to cause confusion or mistake or to deceive as to the origin, sponsorship, or approval of Mezparox and/or Defendants' commercial activities by Sebela and/or the FDA.

94. Additionally, consumers, including purchasers, wholesalers, distributors,

prescribers, insurers, and pharmacists, may be deceived into believing that Mezparox has been approved or authorized by Sebela and/or the FDA.

95. Moreover, Sebela has become uniquely associated with the PRAMOSONE Cream, which association is being unlawfully appropriated and impaired by Defendant.

96. Sebela is likely to and has been damaged by Defendants' conduct, as detailed herein. Sebela is entitled to damages for Defendants' unfair competition, an accounting of profits and recovery of Sebela's costs of this action.

97. Because some of the damage to Sebela's reputation and the reputation of its products cannot be adequately compensated by monetary damages, and Defendants' conduct is causing irreparable and inherently unquantifiable injury and harm to Sebela's business, reputation, and goodwill, Sebela is entitled to temporary, preliminary, and permanent injunctive relief, enjoining Defendants from further unfair competition, including without limitation, removing the false and misleading listings for Mezparox from the Drug Databases.

98. Pursuant to 15 U.S.C. § 1117, Sebela is entitled to recover treble damages sustained by Defendants' actions, an accounting for profits realized by Defendants, and the costs of this action.

99. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Sebela is entitled to an award of reasonable attorney's fees.

COUNT IV

Violation of the Delaware Deceptive Trade Practices Act

100. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs of this Complaint as though set forth fully herein.

101. 6 Del. C. § 2533 provides a private right of action to enforce the provisions of 6

Del C. § 2532.

102. In the course of its business, Defendants have engaged and continue to engage in deceptive trade practices in violation of 6 Del. C. § 2532(a)(1), (2), (3), (5), (7), (9), and (12) by and through their false and misleading representations of fact and conduct with respect to Mezparox.

103. Defendants have willfully engaged in these actions knowing them to be deceptive.

104. By reason of Defendants' actions, Sebela has and will continue to suffer damage to its business, reputation, and goodwill and the loss of sales and profits.

105. Pursuant to 6 Del. C. § 2533, Sebela is entitled to injunctive relief, treble damages, and reasonable attorney's fees.

COUNT V

Common Law Unfair Competition

106. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs as though set forth fully herein.

107. Defendants have intentionally and maliciously made false statements and material omissions in its marketing and sale of Mezparox.

108. Through these actions, as described above, Defendants have wrongfully interfered with Sebela's reasonable business expectancies concerning PRAMOSONE Cream, including expected sales.

109. By reason of Defendants' actions, Sebela has and will continue to suffer damage to its business, reputation, and goodwill and the loss of sales and profits.

110. Sebela is entitled to damages for Defendants' unfair competition, an accounting of profits made on sales of Mezparox and recovery of Sebela's costs of this action. In addition,

Defendants knew or should have known that its conduct was reasonably likely to result in injury, damage or other harm, thus warranting the award of punitive damages.

111. In addition, Defendants' conduct is causing irreparable and inherently unquantifiable injury and harm to Sebela's business, reputation, and goodwill and the reputation of its products that cannot be adequately compensated by monetary damages. Hence, Sebela also is entitled to temporary, preliminary, and permanent injunctive relief, enjoining Defendants from further marketing and sales of the products at issue.

COUNT VI

Tortious Interference with Contract and/or Prospective Contractual Relations

112. Sebela repeats and re-alleges the allegations contained in the preceding paragraphs of this Complaint as though set forth fully herein.

113. Sebela maintains valid contracts and business relations and expectancies with manufacturers, pharmaceutical drug databases, third-party wholesalers, distributors, and pharmacies for the manufacture, purchase, distribution and/or sale of the PRAMOSONE Cream.

114. Upon information and belief, Defendants know of these contracts, business relations, and business expectancies, which are standard in the industry.

115. Upon information and belief, Defendant has acted improperly and without privilege by making false and misleading representations and material omissions in connection with the advertising, marketing and sale of Mezparox in comparison to, and in unlawful competition with, PRAMOSONE Cream.

116. Upon information and belief, Defendant intentionally engaged in such unlawful activities with the intent to disrupt Sebela's contracts and business relations and expectancies for the manufacture, purchase, distribution, and/or sale of the PRAMOSONE Cream.

117. Defendants' intentional interference has induced or caused a breach or termination of Sebela's contracts and business relations and expectancies.

118. By reason of Defendants' interference with its customers, Sebela has and will suffer damage to its business, reputation, and goodwill as well as the loss of sales.

119. In addition, Defendants' conduct is causing irreparable and inherently unquantifiable injury and harm to Sebela's business, reputation, and goodwill and the reputation of its products that cannot be adequately compensated by monetary damages. Hence, Sebela is also entitled to temporary, preliminary and permanent injunctive relief, enjoining Defendants from further interfering with Sebela's customers.

PRAYER FOR RELIEF

WHEREFORE, Sebela prays:

A. That Defendants be required to account to Sebela for any and all profits derived from the sale of Mezparox and to compensate Sebela for all damages sustained by Sebela through the acts complained of herein;

B. That this Court award compensatory, treble, punitive, and exemplary damages in favor of Sebela, including general and specific damages, in an amount to be proven at trial;

C. That this Court order Defendants to engage in corrective advertising to correct all misrepresentations identified herein;

D. That this Court grant temporary, preliminary, and permanent injunctive relief that requires Defendants, and all others acting in privity or in concert with them, to cease making false and misleading representations concerning the product at issue, including without limitation, requiring Defendants to withdraw the listing of Mezparox from the Drug Databases and recall and destroy any remaining product;

E. That the costs of this action be awarded to Sebela;

F. That Sebela be awarded costs and its reasonable attorney's fees as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Delaware law;

G. That this Court grant all other relief to which Sebela may reasonably be entitled under its causes of action; and

H. That this Court grant such other and further relief as it shall deem just, equitable and proper.

Respectfully submitted this 15th day of December 2017.

SEBELA PHARMACEUTICALS INC.

By: /s/ Geoffrey G. Grivner

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